

In re Application of Van Urk *et al.*  
Application No. 09/890,297  
Art Unit No. 1637

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**Amendments to the Claims**

Claims 1 to 151 (canceled)

152. (new) A process for purifying an albumin solution, the process comprising

- (1) subjecting the albumin solution to a first ion exchange chromatography step to yield a first albumin-containing ion exchange product;
  - (2) subjecting the first albumin-containing ion exchange product, with or without intervening purification steps, to a second ion exchange chromatography step to yield a second albumin-containing ion exchange product; and
  - (3) placing the second albumin-containing ion exchange product, without further purification, into a final container for therapeutic use;
- wherein:

- (a) the first ion exchange chromatography step is a cation exchange chromatography step that is run in the negative mode with respect to albumin and the second ion exchange chromatography step is an anion exchange chromatography step; or

- (b) the first ion exchange chromatography step is an anion exchange chromatography step and the second ion exchange chromatography step is a cation exchange chromatography step that is run in the negative mode with respect to albumin; and

wherein the albumin solution is a recombinant albumin solution, and

wherein the albumin solution subjected to the cation exchange chromatography step that is run in the negative mode with respect to albumin has an albumin concentration of 10-250g.L<sup>-1</sup>.

153. (new) The process of Claim 152 wherein the albumin solution subjected to the cation exchange chromatography step that is run in the negative mode with respect to albumin has a pH of 4.5-6.0.

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154. (new) The process of Claim 152, wherein the albumin solution subjected to the cation exchange chromatography step that is run in the negative mode with respect to albumin has an albumin concentration of 20-250g.L<sup>-1</sup>.

155. (new) The process of Claim 152, wherein the albumin solution subjected to the cation exchange chromatography step that is run in the negative mode with respect to albumin has an albumin concentration of 50±10g.L<sup>-1</sup>.

156. (new) The process of Claim 152 wherein the second albumin-containing ion exchange product is subjected to at least one step selected from the group consisting of buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; heating; cooling; and conditioning, before being placed into the said final container.

157. (new) The process of Claim 152 wherein, prior to the second ion exchange chromatography step, the first albumin-containing ion exchange chromatography product undergoes at least one step selected from the group consisting of: buffer exchange; concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent; decolouration treatment; heating; cooling; and conditioning.

158. (new) The process of Claim 152 wherein prior to the cation exchange step the albumin solution undergoes at least one step selected from the group consisting of: (i) pH adjustment; (ii) concentration; (iii) diafiltration; and (iv) conditioning by addition of a fatty acid.

159. (new) The process of Claim 158 wherein prior to the cation exchange step the albumin solution undergoes conditioning by addition of an octanoate salt.

160. (new) The process of Claim 152 wherein the albumin solution subjected to cation exchange chromatography step that is run in the negative mode with respect to albumin has an octanoate ion concentration of 2-15mM.

161. (new) The process of Claim 152 wherein the albumin solution subjected to cation exchange chromatography step that is run in the negative mode with respect to albumin has an octanoate ion concentration of 5-10mM.

162. (new) The process of Claim 152 wherein the anion exchange step is run in the negative mode with respect to the albumin.

163. (new) The process of Claim 163 wherein the albumin solution which undergoes anion exchange chromatography has a pH of 4.0-5.2.

164. (new) The process of Claim 152 wherein the anion exchange step is run in positive mode with respect to the albumin.

165. (new) The process of Claim 164 wherein the albumin solution which undergoes positive mode anion exchange chromatography has a pH of 6.0-8.0.

166. (new) The process of Claim 152 wherein the first ion exchange chromatography step is preceded by at least one step selected from the group consisting of: fermentation; primary separation; concentration; conditioning; cation exchange chromatography; anion exchange chromatography; and affinity chromatography.

167. (new) A process for purifying an albumin solution, the process comprising the steps of:  
(i) subjecting an albumin solution to a cation exchange chromatography step run in positive mode with respect to the albumin;

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- (ii) collecting an albumin-containing cation exchange eluate;
- (iii) subjecting the cation exchange eluate to an anion exchange chromatography step run in positive mode with respect to the albumin;
- (iv) collecting an albumin-containing anion exchange eluate;
- (v) subjecting the anion exchange eluate to an affinity chromatography step run in positive mode with respect to the albumin;
- (vi) collecting an albumin-containing affinity chromatography eluate;
- (vii) subjecting the affinity chromatography eluate to an affinity chromatography step run in negative mode with respect to the albumin and in positive mode with respect to glycoconjugates; and
- (viii) collecting the albumin-containing affinity chromatography flow through;
- (ix) subjecting the affinity chromatography flow through to an ion exchange chromatography step to yield an albumin-containing ion exchange product;
- (x) collecting the albumin-containing ion exchange product from step (ix);
- (xi) subjecting the albumin-containing ion exchange product that is collected in step (x) to a further ion exchange chromatography step to yield a further albumin-containing ion exchange product; and
- (xii) collecting the further albumin-containing ion exchange product from step (xi), thereby to provide a purified albumin solution,

wherein:

- (a) the ion exchange chromatography step of step (ix) above is a cation exchange chromatography step that is run in the negative mode with respect to albumin and the further ion exchange chromatography step of step (xi) above is an anion exchange chromatography step; or
- (b) the ion exchange chromatography step of step (ix) above is an anion exchange chromatography step and the further ion exchange chromatography step of step (xi) above is a cation exchange

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chromatography step that is run in the negative mode with respect to  
albumin; and

wherein the albumin solution is a recombinant albumin solution, and

wherein the albumin solution subjected to the cation exchange chromatography step that  
is run in the negative mode with respect to albumin has an albumin concentration of 10-250g.L<sup>-1</sup>.

168. (new) The process of Claim 167 wherein the anion exchange chromatography step of step  
(ix) or (xi) is run in the positive mode with respect to albumin.

169. (new) The process of Claim 167 wherein the anion exchange chromatography step of step  
(ix) or (xi) is run in the negative mode with respect to albumin.

170. (new) The process of Claim 167 wherein any of the said purification steps are optionally  
preceded or followed by at least one step selected from the group consisting of: buffer exchange;  
concentration; dilution; dialysis; diafiltration; pH-adjustment; treatment with a reducing agent;  
decolouration treatment; heating; cooling; and conditioning.